

**§ 172.590**

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sugar and glutamic acid have been recovered, and which has been subjected to ion exchange to minimize the concentration of naturally occurring trace minerals.

(b) It is used as a flavor in food.

**§ 172.590 Yeast-malt sprout extract.**

Yeast-malt sprout extract, as described in this section, may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is produced by partial hydrolysis of yeast extract (derived from *Saccharomyces cerevisiae*, *Saccharomyces fragilis*, or *Candida utilis*) using the sprout portion of malt barley as the source of enzymes. The additive contains a maximum of 6 percent 5' nucleotides by weight.

(b) The additive may be used as a flavor enhancer in food at a level not in excess of that reasonably required to produce the intended effect.

**Subpart G—Gums, Chewing Gum Bases and Related Substances**

**§ 172.610 Arabinogalactan.**

Arabinogalactan may be safely used in food in accordance with the following conditions:

(a) Arabinogalactan is a polysaccharide extracted by water from Western larch wood, having galactose units and arabinose units in the approximate ratio of six to one.

(b) It is used in the following foods in the minimum quantity required to produce its intended effect as an emulsifier, stabilizer, binder, or bodying agent: Essential oils, nonnutritive sweeteners, flavor bases, nonstandardized dressings, and pudding mixes.

**§ 172.615 Chewing gum base.**

The food additive chewing gum base may be safely used in the manufacture of chewing gum in accordance with the following prescribed conditions:

(a) The food additive consists of one or more of the following substances that meet the specifications and limitations prescribed in this paragraph, used in amounts not to exceed those required to produce the intended physical or other technical effect.

**MASTICATORY SUBSTANCES**

NATURAL (COAGULATED OR CONCENTRATED LATICES) OF VEGETABLE ORIGIN

Family	Genus and species
Sapotaceae:	
Chicle .....	Manilkara zapotilla Gilly and Manilkara chicle Gilly.
Chiquibul .....	Manilkara zapotilla Gilly.
Crown gum .....	Manilkara zapotilla Gilly and Manilkara chicle Gilly.
Gutta hang kang .....	Palaquium leiocarpum Boerl. and Palaquium oblongifolium Burck.
Massaranduba balata (and the solvent-free resin extract of Massaranduba balata).	Manilkara huberi (Ducke) Chevalier.
Massaranduba chocolate .....	Manilkara solimoesensis Gilly.
Nispero .....	Manilkara zapotilla Gilly and Manilkara chicle Gilly.
Rosidinha (rosadinha) .....	Micropholis (also known as Sideroxylon) spp.
Venezuelan chicle .....	Manilkara williamsii Standley and related spp.
Apocynaceae:	
Jelutong .....	Dyera costulata Hook, F. and Dyera lowii Hook, F.
Leche caspi (sorva) .....	Couma macrocarpa Barb. Rodr.
Pendare .....	Couma macrocarpa Barb. Rodr. and Couma utilis (Mart.) Muell. Arg.
Perillo .....	Couma macrocarpa Barb. Rodr. and Couma utilis (Mart.) Muell. Arg.
Moraceae:	
Leche de vaca .....	Brosimum utile (H.B.K.) Pittier and Poulsenia spp.; also Lacmellea standleyi (Woodson), Monachino (Apocynaceae).
Niger gutta .....	Ficus platyphylla Del.
Tunu (tuno) .....	Castilla fallax Cook.
Euphorbiaceae:	
Chilte .....	Cnidioscolus (also known as Jatropha) elasticus Lundell and Cnidioscolus tepiquensis (Cost. and Gall.) McVaugh.

## MASTICATORY SUBSTANCES—Continued

NATURAL (COAGULATED OR CONCENTRATED LATICES) OF VEGETABLE ORIGIN

Family	Genus and species
Natural rubber (smoked sheet and latex solids).	<i>Hevea brasiliensis</i> .
Synthetic	Specifications
Butadiene-styrene rubber .....	Basic polymer.
Isobutylene-isoprene copolymer (butyl rubber).	Do.
Paraffin .....	Synthesized by Fischer-Tropsch process from carbon monoxide and hydrogen which are catalytically converted to a mixture of paraffin hydrocarbon. Lower molecular weight fractions are removed by distillation. The residue is hydrogenated and further treated by percolation through activated charcoal. The product has a congealing point of 93°–99 °C as determined by ASTM method D938–71 (Reapproved 1981), "Standard Test Method for Congealing Point of Petroleum Waxes, Including Petrolatum," a maximum oil content of 0.5 percent as determined by ASTM method D721–56T, "Tentative Method of Test for Oil Content of Petroleum Waxes," and an absorptivity of less than 0.01 at 290 millimicrons in decahydronaphthalene at 88 °C as determined by ASTM method D2008–80, "Standard Test Method for Ultraviolet Absorbance and Absorptivity of Petroleum Products," which are incorporated by reference. Copies may be obtained from the American Society for Testing Materials, 100 Barr Harbor Dr., West Conshohocken, Philadelphia, PA 19428-2959, or may be examined at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <a href="http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html">http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html</a> .
Petroleum wax .....	Complying with § 172.886.
Petroleum wax synthetic .....	Complying with § 172.888.
Polyethylene .....	Molecular weight 2,000–21,000.
Polyisobutylene .....	Minimum molecular weight 37,000 (Flory).
Polyvinyl acetate .....	Molecular weight, minimum 2,000.
PLASTICIZING MATERIALS (SOFTENERS)	
Glycerol ester of partially dimerized rosin .....	Having an acid number of 3–8, a minimum drop-softening point of 109 °C, and a color of M or paler.
Glycerol ester of partially hydrogenated gum or wood rosin.	Having an acid number of 3–10, a minimum drop-softening point of 79 °C, and a color of N or paler.
Glycerol ester of polymerized rosin .....	Having an acid number of 3–12, a minimum melting-point of 80 °C, and a color of M or paler.
Glycerol ester of gum rosin .....	Having an acid number of 5–9, a minimum drop-softening point of 88 °C, and a color of N or paler. The ester is purified by steam stripping.
Glycerol ester of tall oil rosin .....	Having an acid number of 2–12, a softening point (ring and ball) of 80°–88 °C, and a color of N or paler. The ester is purified by steam stripping.
Glycerol ester of wood rosin .....	Having an acid number of 3–9, a drop-softening point of 88 °C–96 °C, and a color of N or paler. The ester is purified by steam stripping.
Lanolin .....	
Methyl ester of rosin, partially hydrogenated .....	Having an acid number of 4–8, a refractive index of 1.5170–1.5205 at 20 °C, and a viscosity of 23–66 poises at 25 °C. The ester is purified by steam stripping.
Pentaerythritol ester of partially hydrogenated gum or wood rosin.	Having an acid number of 7–18, a minimum drop-softening point of 102 °C, and a color of K or paler.
Pentaerythritol ester of gum or wood rosin .....	Having an acid number of 6–16, a minimum drop-softening point of 109 °C, and a color of M or paler.
Rice bran wax .....	Complying with § 172.890.
Stearic acid .....	Complying with § 172.860.
Sodium and potassium stearates .....	Complying with § 172.863.
TERPENE RESINS	
Synthetic resin .....	Consisting of polymers of $\alpha$ pinene, $\beta$ pinene, and/or dipentene; acid value less than 5, saponification number less than 5, and color less than 4 on the Gardner scale as measured in 50 percent mineral spirit solution.
Natural resin .....	Consisting of polymers of $\alpha$ -pinene; softening point minimum 155 °C, determined by U.S.P. closed-capillary method, United States Pharmacopeia XX (1980) (page 961).

MASTICATORY SUBSTANCES—Continued  
NATURAL (COAGULATED OR CONCENTRATED LATICES) OF VEGETABLE ORIGIN

Family	Genus and species
ANTIOXIDANTS	
Butylated hydroxyanisole .....	Not to exceed antioxidant content of 0.1% when used alone or in any combination. Do. Do.
Butylated hydroxytoluene .....	
Propyl gallate .....	
MISCELLANEOUS	
Sodium sulfate .....	Reaction-control agent in synthetic polymer production.
Sodium sulfide .....	

(b) In addition to the substances listed in paragraph (a) of this section, chewing gum base may also include substances generally recognized as safe in food.

(c) To assure safe use of the additive, in addition to the other information required by the act, the label and labeling of the food additive shall bear the name of the additive, “chewing gum base.” As used in this paragraph, the term “chewing gum base” means the manufactured or partially manufactured nonnutritive masticatory substance comprised of one or more of the ingredients named and so defined in paragraph (a) of this section.

[42 FR 14491, Mar. 15, 1977, as amended at 45 FR 56051, Aug. 22, 1980; 49 FR 5747, Feb. 15, 1984; 49 FR 10105, Mar. 19, 1984; 66 FR 38153, July 23, 2001; 66 FR 53711, Oct. 24, 2001]

**§ 172.620 Carrageenan.**

The food additive carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction from the following members of the families Gigartinaceae and Solieriaceae of the class Rhodophyceae (red seaweed):

Chondrus crispus.  
Chondrus ocellatus.  
Eucheuma cottonii.  
Eucheuma spinosum.  
Gigartina acicularis.  
Gigartina pistillata.  
Gigartina radula.  
Gigartina stellata.

(b) The food additive conforms to the following conditions:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 20 percent to 40 percent on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, carrageenan.

**§ 172.623 Carrageenan with polysorbate 80.**

Carrageenan otherwise meeting the definition and specifications of § 172.620 (a) and (b) and salts of carrageenan otherwise meeting the definition of § 172.626(a) may be safely produced with the use of polysorbate 80 meeting the specifications and requirements of § 172.840 (a) and (b) in accordance with the following prescribed conditions:

(a) The polysorbate 80 is used only to facilitate separation of sheeted carrageenan and salts of carrageenan from drying rolls.

(b) The carrageenan and salts of carrageenan contain not more than 5 percent by weight of polysorbate 80, and the final food containing the additives contains polysorbate 80 in an amount not to exceed 500 parts per million.

(c) The carrageenan and salts of carrageenan so produced are used only in producing foods in gel form and only for the purposes defined in §§ 172.620(c) and 172.626(b), respectively.

(d) The carrageenan and salts of carrageenan so produced are not used in foods for which standards of identity exist unless the standards provide for the use of carrageenan, or salts of carrageenan, combined with polysorbate 80.

(e) The carrageenan and salts of carrageenan produced in accordance with this section, and foods containing the same, in addition to the other requirements of the Act, are labeled to show the presence of polysorbate 80, and the label or labeling of the carrageenan and salts of carrageenan so produced bear adequate directions for use.

#### § 172.626 Salts of carrageenan.

The food additive salts of carrageenan may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of carrageenan, meeting the provisions of § 172.620, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of carrageenan to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of carrageenan that dominates the mixture by reason of the modification, e.g., "sodium carrageenan", "potassium carrageenan", etc.

#### § 172.655 Furcelleran.

The food additive furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is the refined hydrocolloid prepared by aqueous extraction of *furcellaria fastigiata* of the class Rhodophyceae (red seaweed).

(b) The food additive conforms to the following:

(1) It is a sulfated polysaccharide the dominant hexose units of which are galactose and anhydrogalactose.

(2) Range of sulfate content: 8 percent to 19 percent, on a dry-weight basis.

(c) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the additive, furcelleran.

#### § 172.660 Salts of furcelleran.

The food additive salts of furcelleran may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive consists of furcelleran, meeting the provisions of § 172.655, modified by increasing the concentration of one of the naturally occurring salts (ammonium, calcium, potassium, or sodium) of furcelleran to the level that it is the dominant salt in the additive.

(b) The food additive is used or intended for use in the amount necessary for an emulsifier, stabilizer, or thickener in foods, except for those standardized foods that do not provide for such use.

(c) To assure safe use of the additive, the label and labeling of the additive shall bear the name of the salt of furcelleran that dominates the mixture by reason of the modification, e.g., "sodium furcelleran", "potassium furcelleran", etc.

#### § 172.665 Gellan gum.

The food additive gellan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a high molecular weight polysaccharide gum produced from *Pseudomonas elodea* by a pure culture fermentation process and purified by recovery with isopropyl alcohol. It is composed of tetrasaccharide repeat units, each containing one molecule of rhamnose and glucuronic acid, and two molecules of glucose. The glucuronic acid is neutralized to a mixed potassium, sodium, calcium, and magnesium salt. The polysaccharide may contain acyl (glyceryl and acetyl) groups as the O-glycosidically linked esters.

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(b) The strain of *P. elodea* is non-pathogenic and nontoxic in man and animals.

(c) The additive is produced by a process that renders it free of viable cells of *P. elodea*.

(d) The additive meets the following specifications:

(1) Positive for gellan gum when subjected to the following identification tests:

(i) A 1-percent solution is made by hydrating 1 gram of gellan gum in 99 milliliters of distilled water. The mixture is stirred for about 2 hours, using a motorized stirrer and a propeller-type stirring blade. A small amount of the above solution is drawn into a wide bore pipet and transferred into a solution of 10-percent calcium chloride. A tough worm-like gel will form instantly.

(ii) To the 1-percent distilled water solution prepared for identification test (i), 0.50 gram of sodium chloride is added. The solution is heated to 80 °C with stirring, held at 80 °C for 1 minute, and allowed to cool to room temperature without stirring. A firm gel will form.

(2) Residual isopropyl alcohol (IPA) not to exceed 0.075 percent as determined by the procedure described in the Xanthan Gum monograph, the "Food Chemicals Codex," 4th ed. (1996), pp. 437–438, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address <http://www.nap.edu>), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html).

(e) The additive is used or intended for use in accordance with current good manufacturing practice as a stabilizer and thickener as defined in §170.3(o)(28) of this chapter. The additive may be

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used in foods where standards of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act do not preclude such use.

(f) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, the name of the additive and the designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

[55 FR 39614, Sept. 28, 1990, as amended at 57 FR 55445, Nov. 25, 1992; 64 FR 1758, Jan. 12, 1999]

## § 172.695 Xanthan gum.

The food additive xanthan gum may be safely used in food in accordance with the following prescribed conditions:

(a) The additive is a polysaccharide gum derived from *Xanthomonas campestris* by a pure-culture fermentation process and purified by recovery with isopropyl alcohol. It contains D-glucose, D-mannose, and D-glucuronic acid as the dominant hexose units and is manufactured as the sodium, potassium, or calcium salt.

(b) The strain of *Xanthomonas campestris* is nonpathogenic and nontoxic in man or other animals.

(c) The additive is produced by a process that renders it free of viable cells of *Xanthomonas campestris*.

(d) The additive meets the following specifications:

(1) Residual isopropyl alcohol not to exceed 750 parts per million.

(2) An aqueous solution containing 1 percent of the additive and 1 percent of potassium chloride stirred for 2 hours has a minimum viscosity of 600 centipoises at 75 °F, as determined by Brookfield Viscometer, Model LVF (or equivalent), using a No. 3 spindle at 60 r.p.m., and the ratio of viscosities at 75 °F and 150 °F is in the range of 1.02 to 1.45.

(3) Positive for xanthan gum when subjected to the following procedure:

### LOCUST BEAN GUM GEL TEST

Blend on a weighing paper or in a weighing pan 1.0 gram of powdered locust bean gum with 1.0 gram of the powdered polysaccharide

to be tested. Add the blend slowly (approximately  $\frac{1}{2}$  minute) at the point of maximum agitation to a stirred solution of 200 milliliters of distilled water previously heated to 80 °C in a 400-milliliter beaker. Continue mechanical stirring until the mixture is in solution, but stir for a minimum time of 30 minutes. Do not allow the water temperature to drop below 60 °C.

Set the beaker and its contents aside to cool in the absence of agitation. Allow a minimum time of 2 hours for cooling. Examine the cooled beaker contents for a firm rubbery gel formation after the temperature drops below 40 °C.

In the event that a gel is obtained, make up a 1 percent solution of the polysaccharide to be tested in 200 milliliters of distilled water previously heated to 80 °C (omit the locust bean gum). Allow the solution to cool without agitation as before. Formation of a gel on cooling indicates that the sample is a gelling polysaccharide and not xanthan gum.

Record the sample as "positive" for xanthan gum if a firm, rubbery gel forms in the presence of locust bean gum but not in its absence. Record the sample as "negative" for xanthan gum if no gel forms or if a soft or brittle gel forms both with locust bean gum and in a 1 percent solution of the sample (containing no locust bean gum).

(4) Positive for xanthan gum when subjected to the following procedure:

#### PYRUVIC ACID TEST

Pipet 10 milliliters of an 0.6 percent solution of the polysaccharide in distilled water (60 milligrams of water-soluble gum) into a 50-milliliter flask equipped with a standard taper glass joint. Pipet in 20 milliliters of 1N hydrochloric acid. Weigh the flask. Reflux the mixture for 3 hours. Take precautions to avoid loss of vapor during the refluxing. Cool the solution to room temperature. Add distilled water to make up any weight loss from the flask contents.

Pipet 1 milliliter of a 2,4-dinitrophenylhydrazine reagent (0.5 percent in 2N hydrochloric acid) into a 30-milliliter separatory funnel followed by a 2-milliliter aliquot (4 milligrams of water-soluble gum) of the polysaccharide hydrolyzate. Mix and allow the reaction mixture to stand at room temperature for 5 minutes. Extract the mixture with 5 milliliters of ethyl acetate. Discard the aqueous layer.

Extract the hydrazone from the ethyl acetate with three 5 milliliter portions of 10 percent sodium carbonate solution. Dilute the combined sodium carbonate extracts to 100 milliliters with additional 10 percent sodium carbonate in a 10-milliliter volumetric flask. Measure the optical density of the sodium carbonate solution at 375 millimicrons.

Compare the results with a curve of the optical density versus concentration of an authentic sample of pyruvic acid that has been run through the procedure starting with the preparation of the hydrazone.

Record the percent by weight of pyruvic acid in the test polysaccharide. Note "positive" for xanthan gum if the sample contains more than 1.5 percent of pyruvic acid and "negative" for xanthan gum if the sample contains less than 1.5 percent of pyruvic acid by weight.

(e) The additive is used or intended for use in accordance with good manufacturing practice as a stabilizer, emulsifier, thickener, suspending agent, bodying agent, or foam enhancer in foods for which standards of identity established under section 401 of the Act do not preclude such use.

(f) To assure safe use of the additive:

(1) The label of its container shall bear, in addition to other information required by the Act, the name of the additive and the designation "food grade".

(2) The label or labeling of the food additive container shall bear adequate directions for use.

### Subpart H—Other Specific Usage Additives

#### § 172.710 Adjuvants for pesticide use dilutions.

The following surfactants and related adjuvants may be safely added to pesticide use dilutions by a grower or applicator prior to application to the growing crop:

*n*-Alkyl ( $C_8$ - $C_{18}$ ) amine acetate, where the alkyl groups ( $C_8$ - $C_{18}$ ) are derived from coconut oil, as a surfactant in emulsifier blends at levels not in excess of 5 percent by weight of the emulsifier blends that are added to herbicides for application to corn and sorghum.

Di-*n*-alkyl ( $C_8$ - $C_{18}$ ) dimethyl ammonium chloride, where the alkyl groups ( $C_8$ - $C_{18}$ ) are derived from coconut oil, as surfactants in emulsifier blends at levels not in excess of 5 percent by weight of emulsifier blends that are added to herbicides for application to corn or sorghum.

Diethanolamide condensate based on a mixture of saturated and unsaturated soybean oil fatty acids ( $C_{16}$ - $C_{18}$ ) as a surfactant in emulsifier blends that are added to the herbicide atrazine for application to corn.

Diethanolamide condensate based on stripped coconut fatty acids ( $C_{10}$   $C_{18}$ ) as a surfactant in emulsifier blends that are